INSTRUCTIONS FOR USE
KRSL-101 Seal Check Indicator

Document No. IFU-KRSL-101 I Revision 1.03 I 06 October 2026

Product code	KRSL-101	**Brand**	EEP
Product type	Type 1 sealing process indicator	**Size**	135 × 165 mm
Supplied as	Non-sterile sheets	**Pack quantity**	200 sheets
Shelf life	36 months from manufacture	**Device class**	Class B, per product listing

1. Intended purpose

KRSL-101 is a single-use Type 1 seal check indicator sheet for routine monitoring of heat-sealing equipment used to close sterile barrier packaging in CSSD and other sterile processing settings. It is intended to make visible deviations in the sealing area and to provide a record of the sealer, operator, date, temperature, pressure and test result. It may also support operational qualification and performance qualification activities when used as part of a documented validation protocol.

The product is intended for use with standard sterile barrier pouches and reels used in sterilization services, including paper/film and Tyvek®/film constructions. The packaging manufacturer's instructions and compatibility requirements remain applicable.

2. Use frequency

- Perform the check each day before routine sealing of sterilization reels or pouches.
- Repeat the check whenever the packaging brand, type or construction is changed.
- Repeat the check after sealer adjustment, maintenance, repair, relocation or other change that may affect sealing performance, according to the facility quality procedure.

3. Instructions for use

- Confirm that the KRSL-101 sheet is within its expiry date and is clean and undamaged. Use one sheet for one test only.
- Prepare a representative pouch or reel of the packaging type and brand that will be used. Follow the packaging manufacturer's instructions for the package and the heat sealer.
- Place one KRSL-101 sheet inside the package with the printed information facing upward and visible through the package film.
- Position the package in the sealer so the sealing seam passes through the designated "Seal Check Indicator" area. Keep the test area aligned with the complete sealing path.
- Operate the sealer using the established settings and routine method for that packaging material. Do not change normal practice solely for the test.
- After sealing, inspect the complete indicator/seal area and the adjoining packaging surfaces. Record the machine, operator, date, temperature, pressure and result in the fields provided on the KRSL-101 sheet.
- Retain the completed sheet in the facility's records. Do not reuse the sheet.

4. Result interpretation

PASS: the indicator response is uniform throughout the seal check area; the packaging film is uniformly bonded to the porous packaging layer along the seal; and the sealed area shows no visible wrinkles, gaps, channels, interruptions or uneven appearance.

FAIL: the indicator response is non-uniform, or the film is not uniformly bonded to the porous layer, or the seal shows wrinkles, gaps, channels, interruptions or other visible unevenness. Mark “Fail” in the result field and do not accept the sealer/package combination for routine use until it has been assessed and a satisfactory check is obtained.

The applicable sterile barrier packaging specification governs the required seal width. For pouches and reels within the scope of EN 868-5, the overall seal width requirement is at least 6 mm; for ribbed seals, the sum of rib widths is at least 6 mm. This dimensional requirement is not a universal acceptance limit for every packaging construction, and KRSL-101 does not replace seal-strength, integrity or other required package validation tests.

5. Action after a failed check

- Stop routine sealing with the affected sealer/package combination and identify the affected machine and packaging material.
- Check the sealer settings and condition, including sealing temperature, contact pressure, dwell time or speed, alignment, and the cleanliness and condition of the sealing elements.
- Check that the packaging material is compatible with the sealer and that the manufacturer’s recommended sealing settings are followed.
- Correct the identified issue and repeat the KRSL-101 check using a fresh sheet before resuming routine sealing.
- If the result remains unacceptable, keep the sealer out of routine use and follow the facility’s maintenance, validation and nonconformance procedures. Document the failure and corrective action.

6. Limitations

- KRSL-101 is a visual process check. It does not by itself prove package sterility or establish the microbiological integrity or strength of a seal.
- The test does not replace installation, operational and performance qualification, periodic requalification, package integrity testing, seal-strength testing, or the packaging/sealer manufacturer’s instructions where these are required.
- A satisfactory result applies to the tested sealer and packaging type/brand under the conditions used for that test. Repeat testing after a packaging brand or type change.
- Use the complete intended seal path and the representative packaging configuration. Do not cut or alter the test sheet in a way that removes the seal check area.

7. Storage, shelf life and disposal

Store sheets at ambient temperature in the original zip-lock packaging. Keep the package closed when not in use. Protect from light, oxidizing agents and disinfectants. The shelf life is 36 months from the date of manufacture. Do not use after the expiry date printed on the package. Dispose of used or damaged sheets according to facility procedures and applicable local requirements.

8. Manufacturer and contact

Legal manufacturer: Krinmed Khavarmianeh Inc.
Brand: EEP
Address: Qarchack Industrial Zone, Tehran, Iran
Email: info@krinmed.com
Telephone: +98 21 4126 9999

9. Standards and references

KRSL-101 is intended to support routine monitoring and documented evaluation of heat-sealing processes. ISO 11607-2 specifies requirements for validation of forming, sealing and assembly processes for packaging of terminally sterilized medical devices; use KRSL-101 within the facility's validated procedures and applicable packaging specifications. EN 868-5 specifies seal construction requirements for the packaging within its scope, including a minimum overall seal width of 6 mm. These standards do not make a visual indicator check a substitute for full process validation.